

**REMARKS****Status of the Claims and Request for Rejoinder**

Claims 7, 11, 12, 14, 19, 22, 23, 36, 37, 41, 42, 46-48, 51, 53, 54, 59, 66, 69, 70, 72-90, 91-94, 112, 113, 114, 115, 117-131 and 133 are pending in the present application. Claim 132 is cancelled. Support for the amendments to the claims includes, but is not limited to, the description in claims 59 and 72 as well as the description bridging the paragraph on pages 18 – 19 of the specification. Support for new claim 133 includes subject matter cancelled from claim 19.

Further, all withdrawn method claims have been amended so as to include the limitations necessary for allowance with respect to the composition claims. Thus, the method claims should be rejoined at this stage.

This amendment places the application into immediate condition for allowance or places the claims in better form for appeal. No new issues are introduced by this claim amendment.

**Interview Summary Record**

Applicants' Representative and Inventor Dr. Karen Brown gratefully appreciate the interview with the Examiner and his SPE. Briefly, Applicants' Representative argued that in order to expedite allowance of the present application, Applicants would amend all claims to emphasize that the purity between the claimed compositions and the prior art was mutually exclusive. Inventor Dr. Karen Brown also agreed to submit Rule 132 Declarations to show that the claimed low purity hyaluronic acid was not commercially available at the time of the present invention and to show that the Monkey Eye test is a well established test that clearly defines the

metes and bounds of the invention.

**Claim Rejections - 35 U.S.C. §112**

The rejection of claim 132 under 35 U.S.C. 112, second paragraph, is moot in view of the cancellation of this claim.

**Claim Rejections - 35 U.S.C. §103**

The Examiner has rejected claims 7, 11, 12, 14, 19, 22, 23, 36, 37, 41, 42, 46-48, 51, 53, 54, 59, 66, 69, 70, 72-94, 112, 113, 114, 115 and 117-132 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,736,024 to Della Valle et al. in view of U.S. Patent No. 4,141,973 to Balazs. This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

**Distinctions Between the Present Invention and Della Valle et al. in view of Balazs**

Each of the present independent claims have been amended to recite the Owl Monkey Eye test, which is used in the present invention as well as in U.S. Patent No. 4,736,024 to Della Valle et al. AND U.S. Patent No. 4,141,973 to Balazs. In contrast to the present invention, which utilizes low purity active ingredient (e.g. HA) as measured by the Owl Monkey Eye test, the cited prior art uses a pure/medical grade hyaluronic acid (HA) that must pass the Owl Monkey Eye test. Clearly, the claimed composition is impure as measured by the well known Owl Monkey Eye test, which is also relied upon by the prior art cited by the Examiner. Thus, the present invention and the cited prior art describe compositions that are mutually exclusive.

Indeed, it is readily apparent that modifying the teachings of the prior art in an attempt to obtain the present invention would destroy the teachings of the prior art. Thus, the rejection is clearly an improper hindsight reconstruction of the prior art in view of Applicants' own disclosure and must be withdrawn.

With respect to the Examiner's comments on page 5, lines 1-5 of the Office Action, the pure vs. low purity argument is not an intended use. Rather, the purity relates to a fundamental property of the composition. This is readily recognized by one of ordinary skill in the art and this is the reason that both U.S. Patent No. 4,736,024 to Della Valle et al. AND U.S. Patent No. 4,141,973 to Balazs utilize the Owl Monkey Eye test to describe their compositions. Applicants are using the identical test to describe the purity of the claimed composition. Purity of a material is clearly not an intended use is evidenced by the prior art relied upon by the Examiner.

With respect to the Examiner's comments in the first full paragraph on page 5 and the first paragraph on page 7 of the Office Action, the ordinary artisan at the time of the invention utilized highly pure HA rather than the claimed low purity HA. This is evidenced by prior rejections [e.g. Balazs] made by another Examiner in the present application and which was overcome by Applicants. Further, low purity HA was not commercially available at the time of the invention which is one reason both Balazs and cosmetic companies at the time of the invention utilized high purity HA. Applicants' position is further supported by Dr. Brown's attached Declaration relating to the costs and availability of HA at the time the present invention was made. Therefore, the Examiner's conclusions are believed to have been adequately addressed and rebutted.

With respect to the Examiner's comments in the last paragraph on page 5 of the Office

Action, Applicants basically agree with the Examiner. That is, the combination of Balazs and Della Valle result in a pure composition. However, such a combination does not teach the present invention, which results in a low purity glycosaminoglycan (eg HA).

Finally, attached is a second Rule 132 Declaration requested by the Examiner. Although Applicants are providing this Declaration, the submission of such a Declaration should be entirely unnecessary. Applicants are using a test that defines the purity of their invention. It is the same test used by the prior art cited by the Examiner. In accordance with the well defined test, Applicants' composition fails the test since it is low purity as defined by the test. Since the test is clear and the cited prior art passes the test whereas the present invention fails the test, this information should be all that is required. However, Applicants are providing the Declaration in an attempt to resolve all outstanding issues.

If the present amendment and remarks does not overcome the outstanding rejections and place the application into condition for allowance, then the Examiner is requested to contact the undersigned at 703-205-8000.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Marc S. Weiner, Reg. No. 32,181 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.14; particularly, extension of time fees.

Dated: March 8, 2010

Respectfully submitted,

By 

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